

June 20, 2023

Ms. Joan Lawrence, ASTM F15.22 Subcommittee Chair Mr. Al Kaufman, ASTM F15.22 Task Group Chair ASTM International 100 Barr Harbor Drive West Conshohocken, PA 19428

Dear Ms. Lawrence and Mr. Kaufman:

On February 7, 2023, CPSC staff¹ sent a letter² to the ASTM F15.22 subcommittee outlining 53 CPSRMS incidents from water bead ingestion, 5 incidents of water bead ear canal insertion, and 4 incidents of water bead nasal cavity insertion. Staff also provided relevant data. As a result, the ASTM subcommittee held an emerging hazards meeting on March 2, 2023, to discuss the letter and data. In that meeting, some task group members asserted that the data did not warrant modifying the current performance requirements or test methods based on two claims: 1) that the products involved in the incidents were not toys, but were used for decorative purposes and 2) that the age of the children involved were all under three years and thus the small parts requirements within the standard should address the ingestion hazard.

CPSC staff further analyzed the CPSRMS incidents related to the water bead hazard to 1) remove any duplicate incidents or secondhand reports, 2) remove out of scope incidents, and 3) remove any product not explicitly marketed as a toy. Staff found a total of 34 incidents involving toys, 1 incident involving non-toys, and 4 incidents where staff could not make a definitive determination at this time. However, CPSC staff disagrees with the assertion that incidents involving water beads that are not explicitly marketed as toys are irrelevant to developing a voluntary standard for water beads that are marketed as toys, where the properties of the water beads and the associated hazard are the same.

The attached data, Table 1, shows 17 of the 34 CPSRMS incident reports involving toys, of which 1 is a near ingestion because a caregiver intervened, preventing an ingestion. The remaining 16 of these incident reports from Table 1 include a total of 19 victims as outlined below:

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¹ The views expressed in this letter are those of CPSC staff, and they have not been reviewed or approved by, and may not necessarily reflect the views, of the Commission.
² <u>https://www.cpsc.gov/s3fs-public/2-7-23-Letter-to-ASTM-Expanding-Materials.pdf?VersionId=J6C99JbHigMfjRMQRBP_N085vcvftuq9</u>



- 10 were ingestion incidents. 9 of these incidents involved children under 3 years old, and 1 incident involved a 4-year-old child.
- 3 were incident reports of ear canal insertion. One incident involved four children, all of which were at least 3 years old.
- 3 incidents involved nasal cavity insertion. All victims were at least 3 years old.

In addition to the 17 reported incidents summarized above, data for the other 17 CPSRMS incidents cannot be provided at this time due to legal restrictions, however, staff provides the following summary of these incidents which involve toys:

- 15 incidents involved ingestion. Among the children involved in the incidents, 7 were under 3 years old, 2 were over the age of 3, and 6 were unknown,
- 1 incident of ear canal insertion, age of the child involved is unknown,
- 1 incident of aspiration, the child involved was 18 months old.

CPSC staff requests that the toy safety F15.22 subcommittee schedule a meeting to discuss the data further and develop more stringent performance requirements to address these incidents. Additionally, CPSC staff is assessing alternative test methods and performance requirements that will be shared prior to the next water bead hazards meeting. If you have any questions, or need additional information about any of these matters, you can contact me at: <u>bmordecai@cpsc.gov</u> or (301) 987-2506.

Sincerely,

Benjamin Mordecai

Benjamin Mordecai Mechanical Engineer Project Manager, F963

Cc: Molly Lynyak, ASTM F15 Staff Manager Susan Bathalon, Children's Program Area Risk Manager Jacqueline Campbell, CPSC Voluntary Standards Coordinator

Enclosure(s):

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Table 1: Water Bead Data

Water Bead Incidents 12/1/2016 - 12/21/2022*

*Based on reports entered into CPSC's CPSRMS database no later than 12/21/2023.

*Disclaimer: CPSC does not guarantee the accuracy, completeness, or adequacy of these data particularly with respect to information submitted by people outside of CPSC. This spreadsheet was prepared by CPSC staff, has not been reviewed or approved by, and may not necessarily reflect the views of the Commission. Pursuant to 17 U.S.C. § 105, there is no copyright in works of the U.S. government. Therefore, this material is in the public domain and may be freely copied or

reprinted.

#	Document #s	Date	Age/Sex	State	Narrative
1	220518HCC1635	12/2016	10 YOM	DC	A 10-YEAR-OLD MALE HAD SURGERY TO REMOVE A FOREIGN BODY MASS IN HIS LEFT EAR AFTER EXPERIENCING SEVERE EARACHES FOR TWO MONTHS. A SURGEON REMOVED AN APPROXIMATELY 9-10 MM GELATINOUS MASS, BELIEVED TO BE A WATER BEAD, FROM THE CHILDÆS EAR. THE MASS DESTROYED THE TYMPANIC MEMBRANE AND TEMPORAL BONE, LEAVING THE VICTIM WITH TOTAL HEARING LOSS IN HIS LEFT EAR.

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2	I22B0199A	1/2017	2 YOF	Unk	An acquaintance I know had a child who swallowed water beads and almost died. She's left with a severe brain injury.
3	180104CBB1236	6/2017	4 YOM	NY	A FOUR YEAR-OLD MALE PLAYING UNSUPERVISED OUTSIDE WITH HIS TWO YEAR-OLD SISTER IN A WATER TABLE FILLED WITH WATER ABSORBING POLYMER BEAD TOYS, PUT AN UNKNOWN NUMBER OF THE WATER-ACTIVATED POLYMER BEAD TOYS UP HIS NOSE. THE VICTIM'S MOTHER, WHO HAD GONE INSIDE THE HOME APPROXIMATELY TWO MINUTES PRIOR TO THE INCIDENT, BECAME AWARE OF THE INCIDENT WHEN HER SON STARTED SCREAMING. A NASAL ENDOSCOPY THE DAY OF THE INCIDENT REVEALED A SMALL BEAD IN THE VICTIM'S NOSE; HOWEVER REMOVAL WAS UNSUCCESSFUL DUE TO BLEEDING. THE VICTIM WAS PLACED UNDER GENERAL ANESTHESIA THE DAY AFTER THE INCIDENT AT A LOCAL HOSPITAL TO REMOVE THE BEAD; HOWEVER AN ENDOSCOPY REVEALED NO BEAD OR FRAGMENTS OF BEAD. IT IS BELIEVED THE VICTIM SWALLOWED AND EVENTUALLY PASSED THE INCIDENT BEAD.
4	170802CCC3140	7/2017	13 MOF	тх	ON JULY [REDACTED] 2017, A 13-MONTH-OLD GIRL BECAME ILL AFTER INGESTING A WATER ABSORBING POLYMER BEAD TOY AT HER HOME. THE BEAD TOY EXPANDED IN HER INTESTINE CAUSING A BLOCKAGE. SHE WAS TRANSPORTED TO A LOCAL HOSPITAL WHERE THE BEAD HAD TO BE SURGICALLY REMOVED. THE GIRL WAS NOT REPORTED TO HAVE SUSTAINED ANY LONG TERM HEALTH EFFECTS FROM THE INCIDENT.

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5	I17B0470A	11/2017	4 YOF	CA	The product [REDACTED] by [REDACTED] imported from China the item looks like candy my 4 year old daughter swallowed one. We went to the emergency department the item does not show up on x-ray. There is no info online about what chemicals are in the product or what she may be exposed to including lead from the paint The hard outer case of just one "gem" dissolves in water into about 50 pieces of hard gelatinous beads. I have no idea how long it takes to biodegrade in my daughter intestines or if she can pass it Poison control was notified by the emergency department I emailed [REDACTED] and have not heard back from them The package states it's biodegradable and non toxic at the top but warning on the bottom that it may contain harmful chemicals and not to ingest. spelling on the package is incorrect making me believe there is little quality control. This company already had one toy recalled for an item that looked like candy and was swallowed by a toddler
6	I17C0113A	11/2017	5 YOF	AR	Me and my niece were playing in my room I had the [REDACTED] and a whole bunch of [REDACTED] in a container that says DO NOT EAT on it (she can read) so I go out of my room to go check on my other niece who is 3 years old I come back just in time to see her grab them she thought they were candy so I had to tell her they were not watch your kids went they play with [REDACTED] they can choke or eat them . So one day she came back over and she ate one but lucky we caught her
7	I1820409A	2/2018	9 YOM	тх	Child snorted [REDACTED] up each nostril. He did not tell us immediately. [REDACTED] swell in the presence of water. When our child told us, his nasal cavity was full of these swollen [REDACTED]. His breathing by nose was completely blocked. My husband removed them tiny piece by piece with tweezers. It took quite a while. We removed all the [REDACTED] from our home. I believe these are dangerous for households with younger and or immature children.

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8	I18C0277A	12/2018	3 ҮОМ	CA	My three and a half year old son stuck a water bead in one of his nostrils. We were unaware it was in his nostril until it came out when he blew his nose very hard. We anticipate he had it in the for about two weeks. During these two weeks he was not able to sleep well at day care or at home. We thought he was sick and was congested. He had a light fever for three days on December 8-10. My son got the water bead at day care where they were using it as a sensory toy. I do not have the package but the bead was small. This is a link to what the items looks like [REDACTED] Day care has removed they toy from the classrooms. I took my son to the pediatrician because his nose was bleeding for a few minutes. No other beads where found. The bead had caused a small tear in the inside of his nostril where it was stuck.
9	I2050104A	3/2020	17 MOM	Unk	A 17 month old male ingested some quantity of [REDACTED] toy water expanding beads. He developed vomiting and parents noticed the beads in his vomit. As his symptoms did not improve he was taken to the emergency room. An x-ray could not visualize any beads or evidence of obstruction. However the patient continue to vomit and was unable to keep down liquids. [REDACTED] were noted to pass in his stool. About 48 hours after he began vomiting he was taken to the operating room as his symptoms persisted. An [REDACTED] ball was seen just past the stomach via endoscopy but was unable to be retrieved. He then underwent surgery to remove 3 balls blocking the small intestine. He subsequently made a good recovery.

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10	210421HCC1751	3/2021	5 YOF	AL	A MOTHER REPORTED THAT WHILE HER FIVE YEAR OLD DAUGHTER WAS PLAYING WITH FRIENDS AT HOME, A TOY BEAD WAS PLACED IN HER DAUGHTER'S EAR, STARTED TO EXPAND, AND BECAME CAUGHT IN HER EAR. SHE WAS TAKEN TO THE DOCTOR TO REMOVE THE TOY BEAD. THE FIVE YEAR OLD GIRL'S EAR DRUM WAS INJURED.
11	220624HCC1849	5/2021	2 YOM	МІ	A TWO-YEAR-OLD MALE VOMITED SEVERAL TIMES AND WAS UNABLE TO KEEP FLUIDS OR FOOD IN HIS STOMACH OVER THE COURSE OF A FEW DAYS. HE WAS TAKEN TO THE HOSPITAL WHERE THEY DISCOVERED HE HAD AN INTESTINAL OBSTRUCTION AND WOULD NEED SURGERY. MULTIPLE SURGERIES WERE REQUIRED TO FULLY REMOVE THE OBJECT, WHICH DOCTORÆS DISCOVERED WAS A WATER BEAD THAT THE VICTIM HAD SWALLOWED. THE VICTIM HAS SINCE RECOVERED BUT WILL REMAIN AT HIGH RISK FOR INTESTINAL OBSTRUCTIONS THE REST OF HIS LIFE. THE VICTIM'S MOTHER PURCHASED THE WATER BEAD AS A SENSORY TOY.
12	I2160387 C I2160387B I2160387D	6/2021	7 YOF 5 YOM 7 YOM 10 YOM	DC	Findings: Four patients have presented to the otolaryngology clinic with destructive otologic findings both on clinical and radiologic exam. Each patient required surgical repair due to long-standing damage caused by this not-so-benign foreign body. Meaning: Water beads are superabsorbant polymers that cause significant damage to the structures of the ear. There should be significant awareness of the damage caused by these seemingly benign children's toys, as their size makes them very conducsive to being placed in the ear canal.

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13	220511HCC3859	7/2021	14 MOF	UT	A 14-MONTH-OLD CHILD SWALLOWED AN EXPANDING WATER BEAD THAT WAS PURCHASED FROM AN ONLINE RETAILER. THE BEAD WAS ONE IN A CONTAINER OF 300 BEADS. THE WATER BEAD EXPANDED INSIDE THE CHILD AND MADE HER VERY SICK. THE CHILD HAD TO UNDERGO SURGERY IN ORDER TO HAVE THE BEAD REMOVED FROM HER STOMACH. OTHER THAN A SCAR ON HER STOMACH, THE CHILD APPEARS TO HAVE ENJOYED A FULL RECOVERY. THE FAMILY'S MEDICAL BILLS ASSOCIATED WITH THE INCIDENT ARE APPROACHING \$40,000.
14	220810HCC1155	5/2022	2 YOM	NC	A TWO-YEAR-OLD BOY SWALLOWED A WATER GEL BEAD AT HIS BIRTHDAY PARTY ON MAY [REDACTED] 2022. UPON COMING IN CONTACT WITH MOISTURE, THE BEAD EXPANDED FROM LESS THAN HALF AN INCH IN DIAMETER TO LARGER THAN TWO INCHES, RESULTING IN A SEVERE INTESTINAL OBSTRUCTION. THE CHILD MADE A FULL RECOVERY AFTER THE BEAD WAS SURGICALLY REMOVED.
15	221107CFE0002	10/2022	11 MOF	ME	AN 11-MONTH-OLD FEMALE WAS ADMITTED TO A LOCAL HOSPITAL IN CRITICAL CONDITION AFTER INGESTING A WATER BEAD TOY THAT CAUSED A COMPLETE BLOCKAGE OF HER INTESTINAL TRACT. AFTER MULTIPLE SURGERIES TO REMOVE THE FOREIGN OBJECT AND TREAT INFECTIONS AND OTHER COMPLICATIONS FROM THE INITIAL INJURY, THE VICTIM WAS RELEASED TO HOME CARE BUT REMAINED ON A FEEDING TUBE.
16	I22B0540A	11/2022	2 YOM	IN	During a sensory play time at daycare a child swallowed a [REDACTED] water bead. He had to have surgery to remove it due to a blocked bowel.

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17 I22C0195A 12/2022 1 YOM VA Post op was rough. He solved him which 1 know he'll be solved how much happing the value of the tolerast of the solut. He heast with the solut which 1 know he'll be solved about. He heast which 1 know he'll be solved book of the value of the value solved has been crying for "book book" so much. If he tole And if he tolerastes for which 1 know he'll be so some solved may a threast of a second well and is able to passe as or bowel movemen home as early as tomorow. Keep the prayers coming please!! I'm ready to take my boy home. I had my instincts which 1'm not great at, and we were blessed to have a tear their gut feelings too. We are just so grateful for a "good" surgery and prayer.	for to be around any child and luring surgery last night. His diately see where the issue was. wetween intestine and the top of y how big this one got while it sat n flushed his intestines and found an issue as the small broken y about his NG tube. Even with on came in right after and saw out for now. I got the go ahead to 't had anything to eat or drink erates it well, he'll get to try food. hts, we may even be able to go d gut feelings and chose to trust m that listened to us AND trusted
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